



PROTOCOL FOR THE NON-DESTRUCTIVE EXAMINATION OF EXPLANTED PRODUCT

The components will be securely wrapped in bubble wrap, each individual piece separately, and packaged in a container that will not pose a biohazard to the shipping agent or the receiver. The package will be sent by Federal Express to DePuy Orthopaedics, Inc., 700 Orthopaedic Drive, Warsaw, IN 46581.

Upon receipt of the package by DePuy Orthopaedics, case identification may need to be established by opening the package to read the enclosed letter, if the information is not described on the package exterior. Once appropriate identification is established, the package will be delivered, with the implants undisturbed within the package, to the Materials Research Laboratory of DePuy. The decontamination process and examinations will be non-destructive in nature.

Procedure:

1. Receive packaged component(s) and may take to our secure Product Complaint vault in the Materials Research Laboratory and have a Product Complaint log number assigned.
2. Prior to decontamination (Step 5), photograph the unopened package to document its exact condition as-received. This photography is conducted in the Macro-Photography Laboratory using a Nikon D3 or F3 35mm camera. Similarly, photograph each step of the un-packaging procedure to document its condition. Additional photos may be taken.
3. Once component(s) are completely unpackaged, photographs will be taken of the component(s) to document their condition. This will be conducted in the same laboratory using a Nikon D3 or F3 35mm camera mounted on an MP-4 photographic stand. Various magnifications will be used depending upon the degree of detail required to document various noteworthy features of the components.
4. Prior to decontamination (Step 5), the product will be examined under a white light source under magnification in the as-received condition. Observations are noted and documented. More photos may be taken.

5. If the product has not been decontaminated, the components comprising of metal shall be steam sterilized or soaked 24 hours in a sterilizing solution of Cidex. Any component containing polyethylene material will be soaked 24 hours in a sterilizing solution of Cidex. Dispose of shipping packaging as hazardous waste.
6. The components will then be taken to the Micro-Photographic Laboratory and optically examined on a Zeiss MZ16 stereomicroscope under white light at magnifications between 10 and 200 times. Noteworthy features will be photographically documented using a Nikon DXM 1200 digital camera, which interfaces with the stereomicroscope.
7. If required, the following non-destructive techniques can be utilized in the investigation:
 - E-SEM (environmental scanning electron microscopy) using the Hitachi S-3500N can be used to aid in determining a mechanism for fracture or alleged failure. Non-metallic surfaces can also be examined using the ESEM without the aid of a conductive coating. The ESEM is a special piece of analytical equipment with an unusually large specimen chamber, which allows examination of large components, precluding the need to modify them to fit into the chamber. The fracture surface, areas near the fracture surface and other noteworthy features of the component will be examined and possibly photographed at magnifications ranging from 50 to 10,000 times. This SEM is also equipped with a state-of-the-art energy dispersive x-ray analyzer, Oxford 7021, which may be used to assess local chemistries in various regions of the component in a completely non-destructive manner.
 - The component(s) may be taken to the Metrology Laboratory for dimensional assessment. The component may be measured using several pieces of equipment including hand-held calipers, a Zeiss Prismo or Eclipse CMM (coordinate measuring machine), and OGP QL-30 optical comparator. These are all non-destructive measuring methodologies.
 - A metallic component may be examined using Zylgo™ fluorescent penetrant inspection, a non-destructive technique to assess for any secondary cracks or surface anomalies.
8. Following all examinations and completion of work, the component is carefully packaged and returned to the appropriate person or entity.